Remarks

In view of the above amendments and the following remarks, reconsideration of the outstanding office action is respectfully requested.

Claims 1-3 are hereby amended and claims 11-13 were previously canceled, so that claims 1-10 and 14-17 are now currently pending. The preamble of claim 1 has been amended to recite that the claimed method is a "method of ***producing a transgenic shrimp***" (emphasis added to show inserted text). Support for this amendment is found throughout the specification, and particularly in the Examples section, beginning at page 19, line 14 and ending at page 35, line 12. Claim 1 has also been amended to add limitations to the "combining" step. These further amendments to claim 1 are discussed below in more detail in response to the pending prior art rejections. Claims 2 and 3 have been amended to replace "egg" with the phrase "transgenic shrimp," thereby clarifying that the nucleic acid molecule delivered into the egg is either heterologous (claim 2) or homologous (claim 3) to the "transgenic shrimp" rather than to the "egg." Support for these amendments is found in the specification at page 24 (Table 1), page 28 (Table 2), and page 34, lines 13-19. Applicant respectfully asserts that no new matter has been added by way of any of the amendments to the claims submitted herewith.

The rejection of claims 1, 2, 4, 6, 7, and 9 under 35 U.S.C. § 102(b) as anticipated by Tseng et al., "Introducing Foreign DNA into Tiger Shrimp (*Penaeus monodon*) by Electroporation," *Theriogenology* 54:1421-1432 (2000) ("Tseng") is respectfully traversed in view of the above amendments and the following remarks.

Tseng discloses using electroporation to introduce a foreign DNA fragment into the fertilized eggs (zygotes) of tiger shrimp (*Penaeus monodon*). The method describe in Tseng (at page 1422) includes the following three general steps: (1) the zygotes are collected 30 minutes after spawning; (2) the zygotes are treated with a buffer to remove their jelly coats; and (3) the treated zygotes are then subjected to electroporation to introduce a foreign DNA fragment into the zygotes. More particularly, Tseng teaches that removal of the jelly coat requires that the zygotes be washed 2 to 4 times with buffer A (2x: 16 g NaCl; 0.4 g KCl; 0.18 g $NaHCO_3$; 0.14 g NaH_2PO_4 with DW dilute 500 mL) at room temperature (at page 1422, paragraph 3). The Examiner has taken the position that the zygotes collected in Tseng had jelly coats that were not fully formed, but only in the process of being formed.

Thus, the Examiner asserts that Tseng teaches the step of independent claim 1 that recites "providing a fertilized shrimp egg prior to its formation of a protective layer." Notwithstanding this assertion, applicant respectfully submits that the present amendments to claim 1 are sufficient to overcome the anticipation rejection based on Tseng, as set forth below.

Claim 1 has been amended to revise the "combining" step to read as follows:

> combining the nucleic acid molecule and the fertilized egg under conditions effective to allow the nucleic acid molecule to be delivered into the egg <u>without removing the protective layer, thereby yielding a transgenic shrimp having the nucleic acid molecule integrated into the genomic DNA of said transgenic shrimp</u>

(underlining added to show inserted text). Support for these amendments is found in the specification as follows: (i) the "without removing the protective layer" limitation is supported in the specification at page 6, lines 14-30, and in the Examples contained in the specification at page 19, line 14 to page 35, line 12; and (ii) the "thereby yielding a transgenic shrimp having the nucleic acid molecule integrated into the genomic DNA of said transgenic shrimp" limitation is supported in the specification at page 24 (Table 1), page 28 (Table 2), and from page 33, line 28 to page 35, line 12.

Claim 1 now specifies that the nucleic acid molecule is delivered into the egg ***without removing the protective layer***. The specification (at page 6, lines 22-23) teaches that the "protective layer" is synonymous to the jelly coat described in Tseng. As noted above, Tseng requires removal of the jelly coat prior to insertion of the foreign DNA into the zygote. Nowhere does Tseng teach insertion of the foreign DNA without removal of the jelly coat. Thus, applicant asserts that the amendments to claim 1 are sufficient to distinguish the method of the rejected claims from the method described in Tseng. Therefore, applicant respectfully submits that the rejection of claims 1, 2, 4, 6, 7, and 9 as being anticipated by Tseng is improper and should be withdrawn.

The rejection of claims 1, 3, 5, 10, and 14–17 under 35 U.S.C. § 103(a) for obviousness over Tseng in view of Godbey et al., "Poly(ethylenimine) and Its Role in Gene Delivery," *Journal of Controlled Release* 60:149-160 (1999) ("Godbey") is respectfully traversed in view of the above amendments and the following remarks. Godbey describes the chemistry relating to poly(ethylenimine) ("PEI") and discusses various PEI/DNA complexes

used for gene delivery. The Examiner states that "there is nothing in the Godbey reference that would suggest that PEI would not successfully work in the production of transgenic shrimp" (Final Office Action, mailed February 14, 2006, at page 5, lines 13-15). However, nowhere does Godbey, alone or in combination with Tseng, teach or suggest using PEI to transfect fertilized shrimp eggs prior to formation of the protective layer and without removal of the jelly coat. Thus, in view of the above amendments to claim 1, applicant respectfully submits that this rejection is improper and should be withdrawn.

In view of all of the foregoing, applicant submits that this case is in condition for allowance and such allowance is earnestly solicited.

Respectfully submitted,

/Andrew K. Gonsalves, Reg. No. 48,145/

Dated: **May 31, 2006**

Andrew K. Gonsalves
Registration No. 48,145

NIXON PEABODY LLP
Clinton Square, P.O. Box 31051
Rochester, New York 14603-1051
Telephone: (585) 263-1658
Facsimile: (585) 263-1600